

## CALIFORNIA PROPOSITION 65

### Introduction

California's Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, is a statute that was placed on the ballot by citizen petition due to concern over inadequate governmental public health regulations. The purpose of the law is to enhance community right-to-know, protect drinking water supplies, and reduce toxic releases. Although the law was opposed by industry and agriculture groups, as well as almost every major newspaper in California, Proposition 65 was approved by the California electorate by nearly a two to one margin.

Proposition 65 mandates that the Governor of California publish a list of chemicals that are known to cause cancer, or been developmental or reproductive toxicity. In addition, warnings must be provided by businesses that knowingly and intentionally expose individuals to these chemicals, unless it is determined that the exposure poses no significant risk assuming a exposure at the level in question for cancer causing chemicals. For chemicals causing reproductive toxicity, businesses that knowingly and intentionally expose individuals to these chemicals must provide warnings, unless it is determined that the exposure will have no observable effects assuming an exposure level 1,000 times the level in question. The warning requirements become effective twelve months after the date of listing of the chemical. Businesses are required to provide a “clear and reasonable” warning, which can take the following forms: labeling a consumer product, posting signs at the workplace/businessplace, or publishing notices in the newspaper. In addition, discharge of these chemicals into drinking water supplies are prohibited twenty months after the date of listing of the chemical, except in those cases where the discharger can demonstrate that the discharge is insignificant. The governor's list currently includes over 580 chemicals, 420 carcinogens, and 160 reproductive toxins. The Act is not applicable to government agencies, drinking water utilities, and businesses employing fewer than ten persons.

### Recent Developments

Following the implementation of the Act, many industries have attempted to avoid or reduce the requirements. The food, drug, and cosmetic industries lobbied to receive a temporary exemption from the law on the grounds that they are already regulated by the US Food and Drug Administration (FDA). In addition, some industry groups tried to avoid having to develop warning labels by setting up a toll-free telephone number for product information which was ruled unacceptable by the courts. By contrast, other industries (such as the tobacco industry) have implemented Proposition 65 warning labels. These labels have added significantly to the scope of hazard warnings on consumer products in California.

Proposition 65 has had some measure of success in influencing the decisions of manufacturers, wholesalers, and retailers, and reducing the risks of chemical exposure. While data are not

currently available on actions taken by the regulated community to remove themselves from the purview of Proposition 65, there is evidence that manufacturers have reformulated products to eliminate or reduce exposures to listed chemicals to avoid having to provide warnings.

Proposition 65's effectiveness as a market-based incentive for the reformulation of products has led to the removal of certain solvents from correction fluids, as well as the removal of lead from certain ceramic products and from foil wraps on wine bottles. In addition, Proposition 65 has been cited as the reason for process modifications, chemical substitutions, and the use of pollution control devices to eliminate or reduce emissions of listed chemicals that would have required warnings.

## **Program Summary**

California EPA's OEHHA is designated as the lead agency for Proposition 65 implementation. OEHHA is "directed to implement the Act in a manner that is fair, predictable, and based on a firm foundation of science." OEHHA compiles the list of carcinogens and reproductive toxins, prepares dose-response assessments on listed chemicals, promulgates regulations, and provides assistance to the regulated community in complying with the law. In addition, the Science Advisory Board (SAB), established by the Governor, reviews chemicals and recommends those to be added to the list. The state's SAB consists of two independent committees of scientists and health professionals that serve as the state's qualified experts; the Carcinogen Identification Committee and the Developmental and Reproductive Toxicant Identification Committee. The authority to enforce Proposition 65 is vested in the Attorney General, local district attorneys, and certain city attorneys. Private citizens may also take action to enforce Proposition 65, following certain conditions (see "Enforcement") (Health and Safety Code, Section 25249.7).

Proposition 65 uses an unusual means of enforcement that allows private citizens to initiate proceedings against alleged violators and reap monetary benefits from successful actions. Sixty days after notifying public authorities (i.e., the Attorney General, the appropriate district attorney, or city attorney) of an alleged violation, any individual or group may sue the offending business if the authorities are not "diligently prosecuting" the matter. If successful, the individual or group bringing suit receives 25 percent of the penalty fines, which may amount to a maximum of \$2,500/day for each violation. The plaintiff filing suit must first show that the alleged violator generated a knowing discharge or exposure. It is then the responsibility of the defendant to prove that the exposures and discharges were within legal limits.

Examples of warnings that have been issued as a result of Proposition 65 include: labels on cigars, pipe tobacco, and other tobacco products not covered by the federal cigarette labeling requirements; point-of-purchase signs warning about risks of alcoholic beverage consumptions during pregnancy; signs warning about the presence of environmental tobacco smoke; and newspaper notices about routine or incidental emissions from facilities in the community.

## Program Methodology

OEHHA compiles and publishes the list of chemicals known to the state to cause cancer or developmental/reproductive toxicity, and updates it at least annually. A chemical is listed:

- 1) if, in the opinion of the "state's qualified experts," the chemical has been clearly shown to cause cancer or reproductive toxicity;
- 2) if an "authoritative" body designated by the "state's qualified experts" has formally identified the chemical as a carcinogen or a developmental/reproductive toxicant; or
- 3) if any state and/or federal agency has formally required the chemical to be labeled or identified as a carcinogen or a developmental/reproductive toxicant.

The "state's qualified experts" have designated the following organizations as authoritative bodies: the US EPA, the FDA, the International Agency for Research on Cancer, the National Institute for Occupational Safety and Health (NIOSH), and the National Toxicology Program.

Additionally, there are two business requirements as part of the rule. First, twelve months after a chemical is listed, businesses must not knowingly and intentionally expose any individual to a listed chemical without first providing a "clear and reasonable warning," unless the business can demonstrate that the exposure:

- does not exceed 1/1000 of the "no observable effect level" (NOEL) for reproductive toxins;
- poses "no significant risk" of cancer. "No significant risk" is defined as the level that results in a cancer risk of less than one excess case of cancer per 100,000 individuals exposed over a 70-year lifetime for carcinogens. In other words, if you are exposed to the chemical in question at this level every day for 70 years, your chances of getting cancer will be no more than 1 case in 100,000 individuals so exposed.

The second business requirement stipulates that twenty months after the chemical is listed, businesses must not knowingly discharge the chemical into the drinking water supply unless the discharger can demonstrate that a "significant amount" of the listed chemical has not, did not, or will not enter any drinking water source and that the discharger complies with all other applicable laws, regulations, permits, requirements or orders. "Significant amount" refers to any detectable amount, unless the resulting exposure meets the same criteria for exemptions from the warning requirement.

## References

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Kizer, Kenneth W., et al., 1988. "Sound Science in the Implementation of Public Policy: A Case Report on California's Proposition 65", *The Journal of the American Medical Association*, August 19, 260 (7): 951-955.